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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,487	02/10/2004	Denise L. Faustman	00786/457003	1044

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EXAMINER	
RINAUDO, JO ANN S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,487	FAUSTMAN ET AL.	
	Examiner	Art Unit	
	Jo Ann Rinaudo	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *76-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 77, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is TNF-α, classified in class 424, subclass 85.1.

II. Claim 78, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antibody directed against IkB, classified in class 424, subclass 130.1.

III. Claim 78, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antibody directed against one of the 240 kD or 200 kD human erythrocyte derived proteasome inhibitors, classified in class 424, subclass 130.1.

IV. Claim 78, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antisense RNA molecule directed against IkB, classified in class 514, subclass 44.

V. Claim 78, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antisense RNA molecule directed against one of the 240 kD or 200 kD human erythrocyte derived proteasome inhibitors, classified in class 514, subclass 44.

VI. Claim 78, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is a ribozyme directed against IkB, classified in class 514, subclass 44.

VII. Claim 78, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, by administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is a ribozyme directed against one of the 240 kD or 200 kD human erythrocyte derived proteasome inhibitors, classified in class 514, subclass 44.

VIII. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is TNF-α, classified in class 424, subclass 85.1.

IX. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antibody directed against IkB, classified in class 424, subclass 130.1.

X. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antibody directed against one of the 240 kD or 200 kD human erythrocyte derived proteasome inhibitors, classified in class 424, subclass 130.1.

XI. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of

NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antisense RNA molecule directed against IkB, classified in class 514, subclass 44.

XII. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is an antisense RNA molecule directed against one of the 240 kD or 200 kD human erythrocyte derived proteasome inhibitors, classified in class 514, subclass 44.

XIII. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is a ribozyme directed against IkB, classified in class 514, subclass 44.

XIV. Claim 82, drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB, wherein said substance is a ribozyme directed against one of the 240 kD or 200 kD human erythrocyte derived proteasome inhibitors, classified in class 514, subclass 44.

2. Claims 76, 79 and 80 link inventions I-VII and Claim 81 links inventions VIII-XIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 76, 79, 80, and 81. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are

presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Groups I-VII and Groups VIII-XIV are different methods. Groups I-VII are drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease by administering a substance that stimulates a signaling pathway that activates NFkB. Groups VIII-XIV are drawn to a method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB. Thus, the methods differ with respect to the method steps; therefore, each method is patentably distinct. Furthermore, the distinct method steps require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

4. Group I, Groups II-III, Groups IV-V, and Groups VI-VII are different methods. The method of treating a mammal having, or predisposed to having an autoimmune disease by administering a substance that stimulates a signaling pathway that activates NFkB by administering TNF-α (Group I), an antibody (Groups II-III), an antisense RNA molecule (Groups IV-V), or a ribozyme (Groups VI-VII). The method steps differ with respect to one or more of the ingredients. Proteins, antibodies, nucleic acids and ribozymes differ with respect to their structures, physicochemical properties and/or mode of action, and they do not share a common structure that is disclosed to be essential for common utility; therefore each method is patentably distinct. Group II is distinct from Group III, because the antibodies used in each method are different and each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site. Group IV is distinct from Group V because the antisense RNA molecules, used in each method, are different nucleic acid sequences. Group VI is distinct from Group VII because the ribozyme molecules, used in each method, recognize different RNA sequences. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each method is patentably distinct, and searching of these Groups would impose an undue burden.

5. Group VIII, Groups IX-X, Groups XI-XII and Groups XIII-XIV are different methods. The method of treating a mammal having, or predisposed to having an autoimmune disease, comprising the steps of measuring the activity of NFkB and if the activity is less than a basal level, administering a substance that stimulates a signaling pathway that activates NFkB by administering TNF-α (Group VIII), an antibody (Groups IX-X), an antisense RNA molecule (Groups XI-XII), or a ribozyme (Groups XIII-XIV). The method steps differ with respect to one or more of the ingredients. Proteins, antibodies, nucleic acids and ribozymes differ with respect to their structures, physicochemical properties and/or mode of action, and they do not share a common structure that is disclosed to be essential for common utility; therefore each method is patentably distinct. Group IX is distinct from Group X, because the antibodies used in each method are different and each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site. Group XI is distinct from Group XII because the antisense RNA molecules, used in each method, are different nucleic acid sequences. Group XIII is distinct from Group XIV because the ribozyme molecules, used in each method, recognize different RNA sequences. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each method is patentably distinct, and searching of these Groups would impose an undue burden.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

7. If Applicant elects **ONE** specific Group from Groups I-VII, Applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no

generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

Applicant is required to elect **ONE** specific disease from the specific diseases recited in Claim 80.

These species of diseases are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

8. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jo Ann Rinaudo, Ph.D.
Patent Examiner
02/15/06

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